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SPECIFICATION FOR
GAG, MOUTH, CLEFT PALATE

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SPECIFICATION FOR GAG, MOUTH, CLEFT PALATE

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Indian Standard

SPECIFICATION FOR GAG, MOUTH, CLEFT PALATE

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 27 October 1966, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Consumer Products Division Council.

0.2 The formulation of Indian Standards on surgical instruments has been taken up on the recommendations of the Advisory Committee for Development of Surgical Instruments, Medical Equipment and Hospital Appliances of the Ministry of Industry, Government of India.

0.3 This standard is one of a series of Indian Standards on surgical instruments. Other standards published so far in the series appear on page 8.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers the requirements of mouth gag used in plastic surgery.

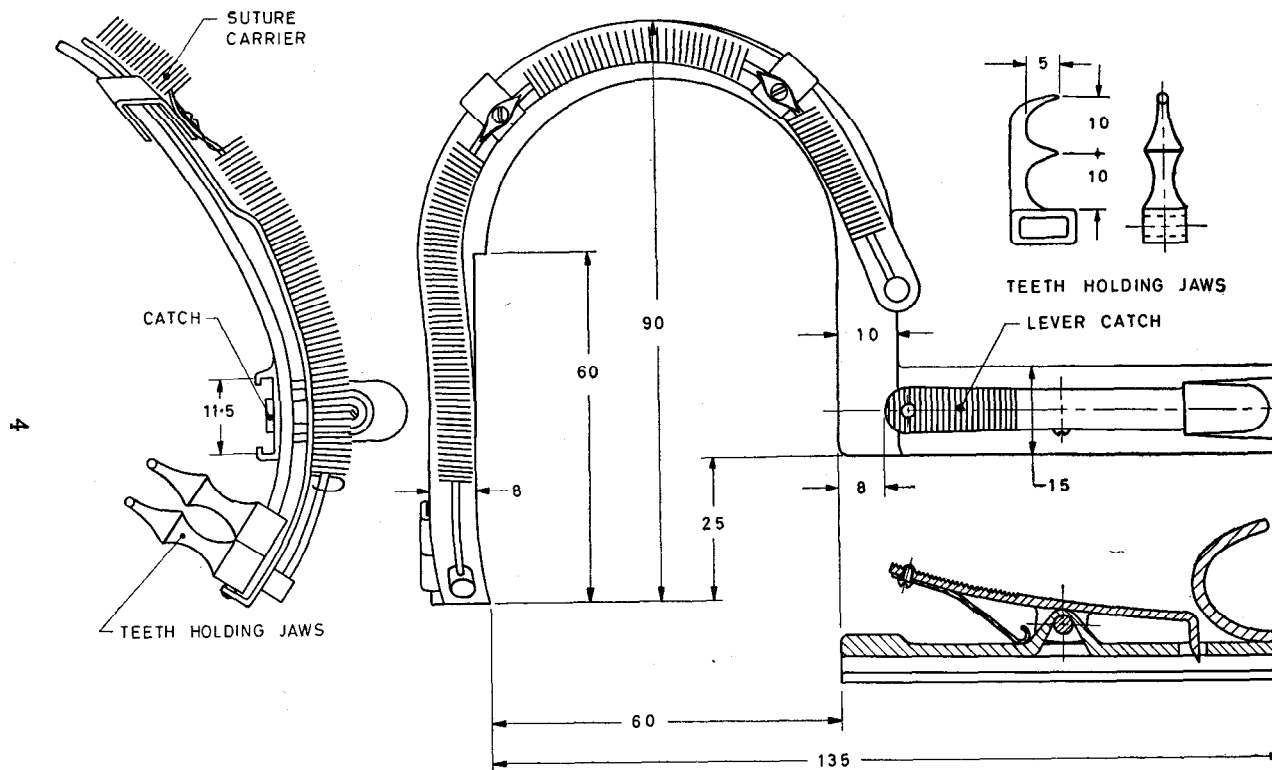
2. MATERIAL

2.1 The frame and blade shall be made from stainless steel conforming to designation 30Cr13 of Schedule V of IS : 1570-1961†.

2.2 Wire used in suture carrier and the spring actuating the lever catch shall be made from hard-drawn steel conforming to designation 30Cr13 or 22Cr13 of Schedule V of IS : 1570-1961†.

*Rules for rounding off numerical values (*revised*).

†Schedules for wrought steels for general engineering purposes.

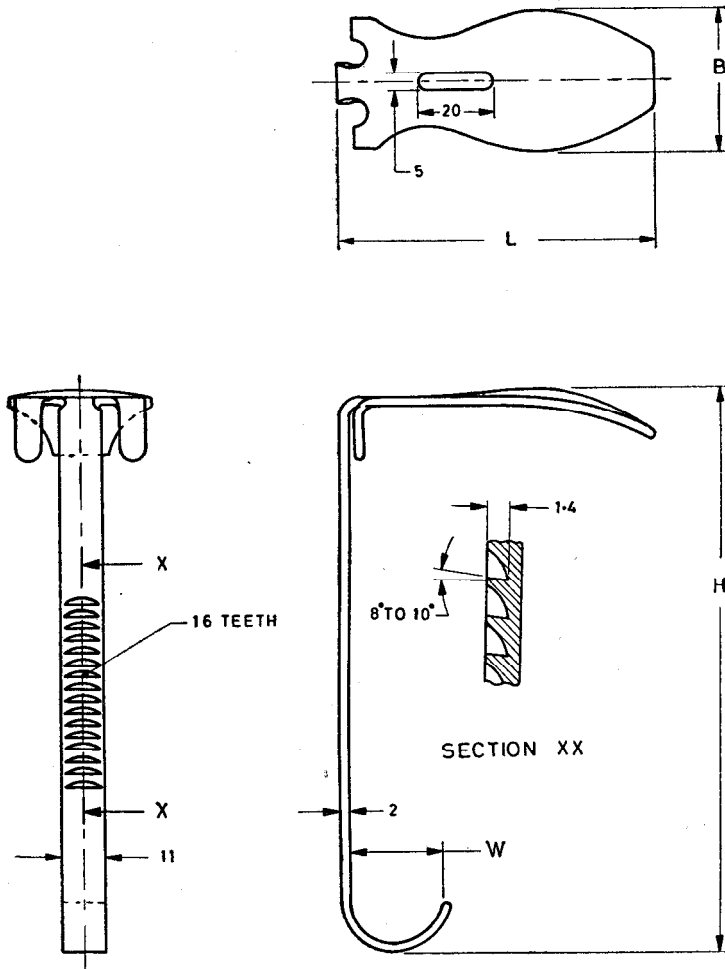


All dimensions in millimetres.

FIG. 1 MOUTH GAG FRAME CLEFT PALATE

3. SHAPE AND DIMENSIONS

3.1 The shape and dimensions of the cleft palate mouth gag frame and three sizes of blade shall be as shown in Fig. 1 and 2 and Table 1. The three blades shall be so made as to facilitate nesting. When the blades nest, they shall be easily removable but shall not dislodge by their own weights.



All dimensions in millimetres.

FIG. 2 MOUTH GAG BLADE

TABLE 1 DIMENSIONS OF THE MOUTH GAG BLADE

OVERALL HEIGHT OF BLADE, <i>H</i>	BLADE LENGTH, <i>L</i>	MAXIMUM WIDTH OF BLADE, <i>B</i>	WIDTH OF FINGER LOOP, <i>W</i>
(1)	(2)	(3)	(4)
mm	mm	mm	mm
142	65	30	17
146	75	35	23
150	85	40	27

4. HEAT-TREATMENT

4.1 The suture carrier and the lever catch springs shall be hardened and tempered so as to stand the test specified in 8.2 and 8.3.

5. WORKMANSHIP

5.1 The blade of the mouth gag shall move in the groove of the frame evenly without shake or play. The blade shall have ratchet teeth as shown in Fig. 2 each of which shall so match with the end of the catch that it shall not slip when it is engaged. The catch shall be capable of operation by means of a spring actuated lever and shall be capable of holding the blade firmly. The teeth holding jaws shall move in the frame evenly and finely at least for a frame length of 70 mm and shall be capable of holding the teeth when the gag is in use. The suture carrier springs shall have guide wires running inside them and shall be anchored only at one end each, facilitating opening of the springs. They shall be mounted on a frame corresponding in shape to the gag and fixed on the gag by means of suitable clips. The lever shall be capable of being pressed fully when a load of 600 to 700 g is applied to the extreme part of the lever.

6. FINISH

6.1 The frame and blade shall be passivated and highly polished and free from any blemishes, burrs and sharp edges.

7. MARKING

7.1 Each mouth gag shall be clearly and indelibly marked with the manufacturer's name, initials or trade-mark and the country of origin.

7.1.1 The mouth gag may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8. TESTS

8.1 Corrosion Resistance Test — The mouth gag shall be tested for corrosion resistance as prescribed in **8.1.1**.

8.1.1 Copper Sulphate Test — The sample shall be scrubbed with soap and warm water, rinsed in hot water, followed by a dip in ethyl alcohol (95 percent) and dried. The sample shall be completely immersed in copper sulphate solution at room temperature for 6 minutes and shall then be washed off with fresh water or with wet cotton wool. The copper sulphate solution shall be made up as follows:

Copper sulphate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$)	4.0 g
Sulphuric acid (H_2SO_4) (sp gr 1.84)	10.0 g
Water (H_2O)	90.0 ml

There shall be no red stains or spots on the sample after the test, but the polished surface becoming dull may be permitted.

8.2 Test on Suture Carrier Spring — Each spring shall be pulled longitudinally so that it is expanded to double its length and released. This shall be repeated 50 times. There shall be no permanent set on the spring after the test.

8.3 Test on Lever Catch Spring — The lever shall be pressed fully so that the spring is compressed to the maximum and released. This shall be repeated 50 times. There shall be no permanent set on the spring after the test.

9. PACKING

9.1 The mouth gag frame and the blades shall be individually wrapped in tissue paper and the three blades nested together. These shall then be packed suitably in cardboard box taking care that the various parts do not knock against each other.

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